

REMARKS

Priority claim

Attached, a copy of a "Notification concerning submission or transmittal of priority document" received from WIPO dated April 27, 2005 was received, confirming that the priority document was timely filed within the 16 month deadline in the underlying PCT application and should therefore fulfill the requirements under Rule 17.1 PCT. A copy of the priority document is available on the official WIPO website at www.wipo.int. The downloaded document is also attached to this reply. In this connection, as is referred to in MPEP 1828, third paragraph, confirming that in case the priority document was filed within the 16 month deadline from the priority date, that *"The IB will normally furnished copies of the certified copy to various designated offices so that the applicant will not normally be required to submit certified copies to each designated office."* More specifically under MPEP 1893.03(c) it is specifically stated under the headline II. THE CERTIFIED COPY in the lower half of the first paragraph:

"The U.S. Patent and Trademark Office, as a Designated Office, will normally request the International Bureau to furnish the copy of the certified priority document upon receipt of applicant's submission under 35 U.S.C. to enter the U.S. national phase. The copy from the International Bureau is placed in the U.S. national stage file. The copy of the priority document received from the International Bureau with either of the indications above is acceptable to establish that applicant has filed a certified copy of the priority document. The examiner should acknowledge in the next Office action that the copy of the certified copy of the foreign priority document has been received in the national stage application from the International Bureau."

If in addition to the submitted evidence and the copy of the priority document that has been downloaded from the official WIPO website, a certified copy still needs to be filed for perfecting the priority claim for the purposes of the U.S. national phase, advise from the Examiner is respectfully requested.

Claim Numbering

The new set of claims reverts back to the original numbering as it was referred to in the Office Action dated December 24, 2009. Proper status identifiers have been included. It is noted that the previous preliminary amendment dated August 2, 2006 comprised prematurely renumbered claims. The numbering in the present claims goes back to the original numbering used in the underlying WO publication WO2005/077289. The amended claims that were presented with the preliminary amendment dated August 2, 2006 should have correctly been numbered new claims 9-12 instead of new claims 4-7 and instead of new claim 9, correctly new claim 13. The remaining claims 1 - 8 should have maintained their original numbering 1 - 8. It appears from the Office Action that the Examiner has assumed this correct numbering. We apologize for any inconvenience the previous premature renumbering may have caused.

35 USC Section 112

In claim 1, the expression "which device" has been substituted by "said device", and the expression "which member" has been substituted by "said member", indicating that the "same" device and member as aforementioned are referred to.

Previously amended claim 5 has now been made dependent on the previously presented claim 13 claiming the clamping means, so that the expression "the clamping means" in claim 5 finds proper antecedent basis in claim 13. The previous lack of antecedent basis was a result of the previous renumbering in the preliminary amendment.

Previously amended claim 6 has now been made dependent on the previously presented claim 13 claiming "the U-shaped projection portion", so that the expression "the U-shaped projection portion" in claim 6 finds proper antecedent basis in claim 13. The previous lack of antecedent basis was a result of the previous renumbering in the preliminary amendment.

Previously amended claim 8 has now been made dependent on the previously amended claim 7 depending from claim 6 that is dependent on previously presented claim 13 claiming "the clamping means", so that the expression "the clamping means" in claim 8 now finds proper antecedent basis in claim 13 via claims 6 and 7. The previous lack of antecedent basis was a result of the previous renumbering in the preliminary amendment.

35 USC Section 102

As indicated in the specification, the invention aims to create a partial or full reinforcement for one sternal half or both. It further provides a sternum reinforcing device that avoids rubbing of any elements such as traditionally used wire on the sternum, and therefore avoids subsequent lesions and consequently avoids partial or complete fractures and wire loosening.

According to the invention as defined by the subject matter claimed in claim 1 put in simple language, a module (in the claim named "elongated member") is claimed that can be combined with other modules to form the "reinforcing group" as claimed in claim 1 that extends in its implanted stage attached to an anterior longitudinal lateral edge of a sternum. Further, this module comprises a projecting portion that is designed to be fitted into an intercostal space. The projecting portion extends between the ribs of the patient. According to a preferred embodiment, this project portion can be designed as a U-shaped body part denoted with reference numeral 4 in the drawings, and may additionally comprises bendable arms 20, 30.

The Examiner rejected claim 1 as lacking novelty in light of each Assaker (U.S. 5,620,444), Longfellow (U.S. 2,486,303) and Miller (U.S. 6,540,769).

As a preliminary consideration, it is noted that neither Assaker nor Longfellow relate to a device suitable to be used onto the sternum. None of these two documents mention the sternum or suggests/implies a possible application to it. Accordingly, none of these two documents discloses the

following, claimed technical features:

- a *sternum* reinforcing device
- an elongated member *designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum*,
- first and second connection parts *apt to connect along the longitudinal lateral edge of the sternum*,
- a projecting portion *designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum*.

Miller is the only cited prior art reference that deals with the sternum. While it may arguably be viewed as a hypothetical starting point of the invention, Miller lacks specifically to teach any modular device allowing to combine the modules that is subjected to the present invention. Miller will be discussed in further detail below.

Novelty of the subject matter of claim 1 over Assaker

Assaker discloses a spinal osteosynthesis device, which, in the embodiment shown in Fig. 14 addressed by the Examiner, is made of a bent rod 32 which slidingly bears anchorage hooks 29 (column 6, lines 6-7).

In addition to the differences in comparison to the claimed invention already pointed out in the previous section above, it must be noted that the circular shape of both the rod and the hooks of Assaker makes them totally unsuitable for the claimed location upon the sternum.

In contrast to the Examiner's conclusions, it is respectfully believed that the only component which is apt to be connected with two members by means of "arms" in Assaker is the rod. However, when the rod is regarded as the claimed "*elongated member*", then it must be noted that the two members

to which it connects, namely two consecutive hooks, do not “*precede*” and “*follow*” the rod itself, contrary to the claimed arrangement.

Moreover, comparing the rod in Assaker to the claimed elongated member, the rod definitely lacks the claimed projecting portion fitting in the intercostal space. If, vice-versa, the elongated member is to be read into a single hook, then the latter does not incorporate any means for connecting with another hook, either preceding or following it.

In summary, Assaker claims a completely different medical device that is used for a completely different purpose, namely as a spinal implant where hooks connect to the vertebrae, and it does not teach any modular design allowing several allocated members to be combined to a larger implant as needed.

Novelty of the subject matter of claim 1 over Longfellow

Longfellow discloses a surgical device for bone fractures, specifically those of femur or humerus (column 1, lines 1 to 3).

The medical device as taught by Longfellow is made of two mating metallic plates A and B of an arcuate shape. The plates have inturned flanges 8 and 10 which, in use, are overlapped. (From column 1, line 45, to column 2, line 8).

In addition to the differences with the claimed invention already pointed out above, it is to be noted that also the plates A and B of Longfellow appear unsuitable for application onto the sternum and Longfellow does not even suggest any meaningful way how to attach this device to a sternum and what purpose it could possibly serve when applied to a sternum.

Moreover, none of such plates is suitable for connection with two other members, one preceding and the other following it, contrary to the claimed arrangement.

Finally, it is respectfully disagreed with the Examiner that the screws 14 of Longfellow are comparable to “*projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum*”. In particular, the screws are not “*projections of the elongated members*”, as these are in contrast distinct elements from the plates and not part of these plates.

Novelty of the subject matter of claim 1 over Miller

Miller relates to a device applicable to the sternal halves in order to close them. This device is made of two parts interconnecting one with the other in the transverse direction of the sternum, not as claimed in present claim 1 along the longitudinal lateral edge of the sternum. Accordingly, Miller does not disclose, for each unit-device, two connection parts apt to connect longitudinally along the sternum with analogous adjacent devices. Moreover, Miller does include only one connection arm per unit-device.

Put in different words, Miller teaches several discrete elements, and therefore might at best be a hypothetical starting point of the present invention. In contrast to Miller, the present invention teaches as claimed in claim 1 that connecting arms of one module can be attached to an adjacent module and so on for building the entire reinforcing group as specified in claim 1 that also comprised the projecting portions that in the assembled and implanted state of the reinforcing group extend into the intercostal spaces.

Miller does not even teach a “sternum reinforcing device”, but as Miller names it, a “sternum closure device”. This is a significant distinction since discrete elements that are attached in a distance to each other and just designed to hold the sternum halves together are not meant to provide reinforcement and will not as these are not designed to build a uniform reinforcing group that is assembled during the implantation process for the purpose of forming the larger reinforcing group that extends along the

longitudinal lateral edge of the sternum, as for instance Fig. 11 of the present invention demonstrates.

Miller particularly provides an indications that the prior art has not thought in direction of the invention, but offers only discrete elements or wire that holds the sternum parts together, but fails to reinforce these sternum halves.

Novelty of the subject matter of dependent claims 2 – 13 over Assaker, Longfellow and Miller

Since the subject matter of present claim 1 is new, also all combinations with the dependent claims are novel. Particularly pointing out some features, no coupling whatsoever in the cited prior art teaches a prismatic coupling allowing coupling of one element to a preceding and a following elongated member (claim 2). It was novel to form such element from a bent plate material (claim 3). The prior art does not teach projecting portions (claim 4). Although the specification acknowledges that wire was used in prior art, it was not used to clamp the elements on opposing sides of the sternum together, particularly not for clamping the U-shaped projecting portions together (claims 13, and 6). No disclosure can be found in the cited prior art about the splint (claims 7 and 8). Last not least, the specific form of the arms of the elongated members that attach to each other for forming the reinforcing group from the individual members was not taught in prior art (claims 8 to 12).

35 USC Section 103

Claim 5 was rejected over Assaker in view of Wagner. It is respectfully disagreed that Assaker teaches a wire. Reference numeral 25 designates a “tubular rod 25” as it is named literally in the specification. Not only the expression “tubular rod”, but also the function to reinforce the spine makes it clear that the skilled person would not understand it as a “wire”, even less so when it is “tubular” and has to be rigid enough to reinforce a spine. In addition, Assaker does not teach to clamp sternum halves together, let

alone reinforcing elements on opposite sides of the sternum, so even if it is assumed that the tubular rod is the same as a wire, this still does not render the subject matter of claim 5 obvious.

Although not rejected under 35 USC 103, also claims 1-4 and 6-13 are non-obvious. The cited prior art fails to even mention the aim to reinforce the sternum, and accordingly does not teach any applicable teaching that would achieve this goal. Miller, the only cited prior art dealing with the sternum at all, fails teaching elongated members that can be assembled to a reinforcing group that extends along the lateral edge. The remaining cited prior art references are in no way adapted to even be attached to the sternum, and if attached, would create major problems like lesions to the sternum as these are not adapted to be attached in such a manner that a sternum that is subject to constant movement due to breathing motion of the patient would tolerate installation like inappropriate rods and hooks.

Conclusion

Applicant respectfully requests that the Examiner issue a Notice of Allowance for the pending claims 1 – 13. Should the Examiner require further information, the Examiner is invited to contact the Applicant's representative at the number listed below.

Enclosures: - Downloaded priority document IT RM2004A000082
- Copy of form PCT/IB/304 "Notification concerning submission or transmittal of priority document"

Respectfully submitted,

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Alexander R. Schlee
Reg. No. 55,912

Alexander R. Schlee
Schlee IP International P.C.
3770 Highland Ave., Suite 203
Manhattan Beach, CA 90266
Tel: (310) 545-9851
Fax: (310) 545-9853